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(54) **SYSTEMS AND METHODS FOR USE IN SPINAL SUPPORT**

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See application file for complete search history.

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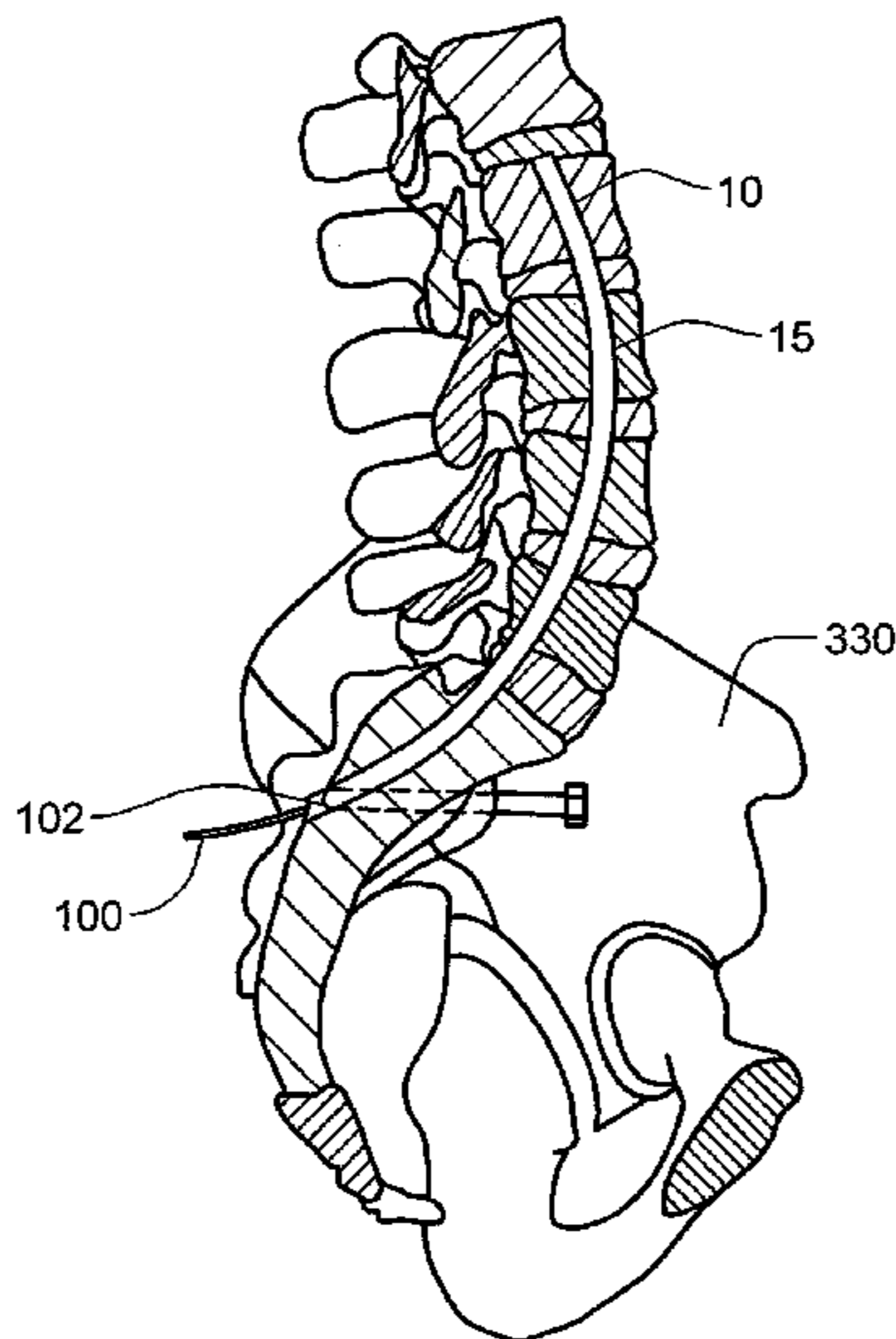
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(57) **ABSTRACT**

A method for supporting a spine of a person includes forming a pathway in a spine by removing a plurality of portions of a plurality of vertebrae of the spine with the pathway being configured to receive a supporting structure. The supporting structure is inserted into the pathway and through the plurality of vertebrae.

25 Claims, 5 Drawing Sheets



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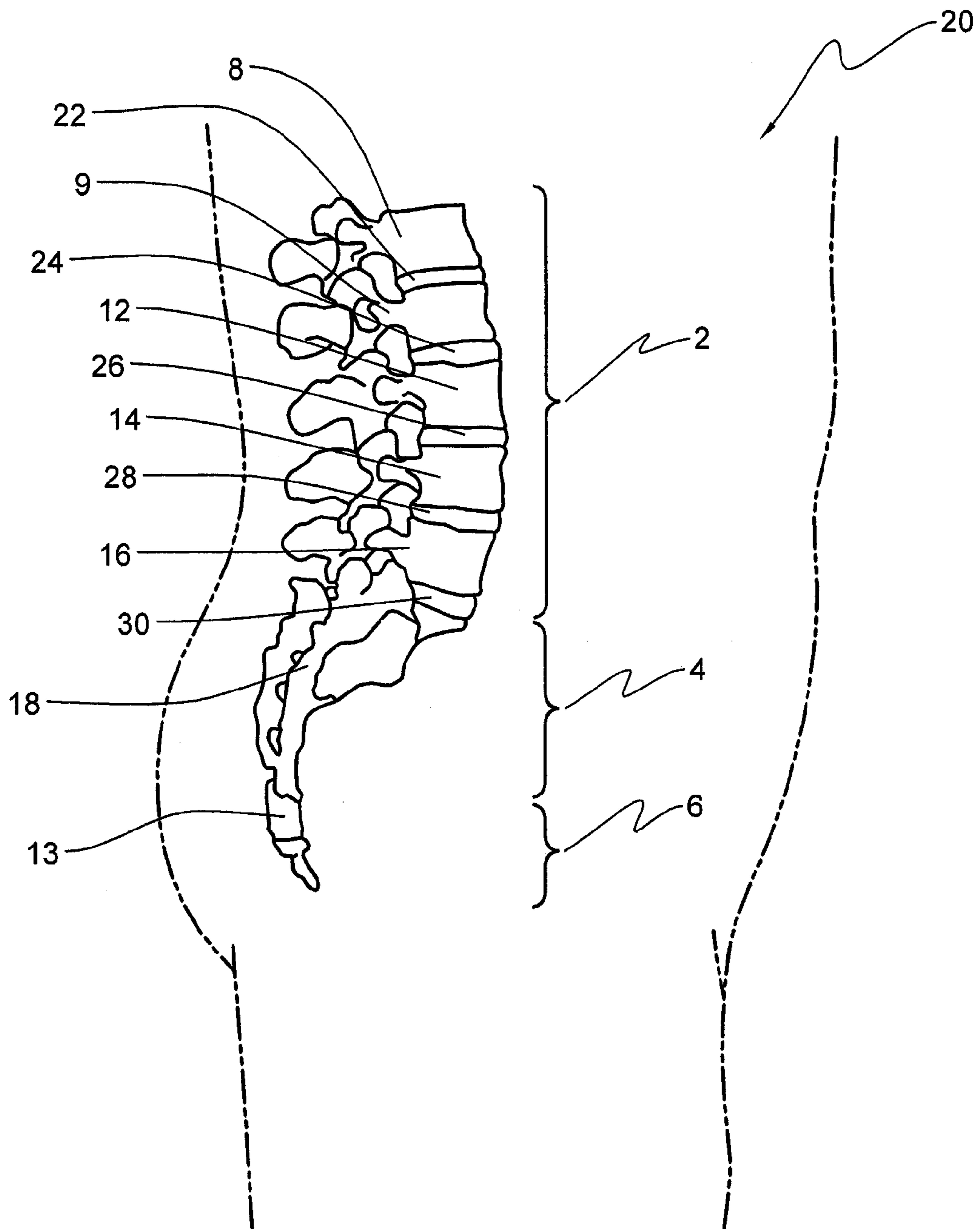


FIG. 1

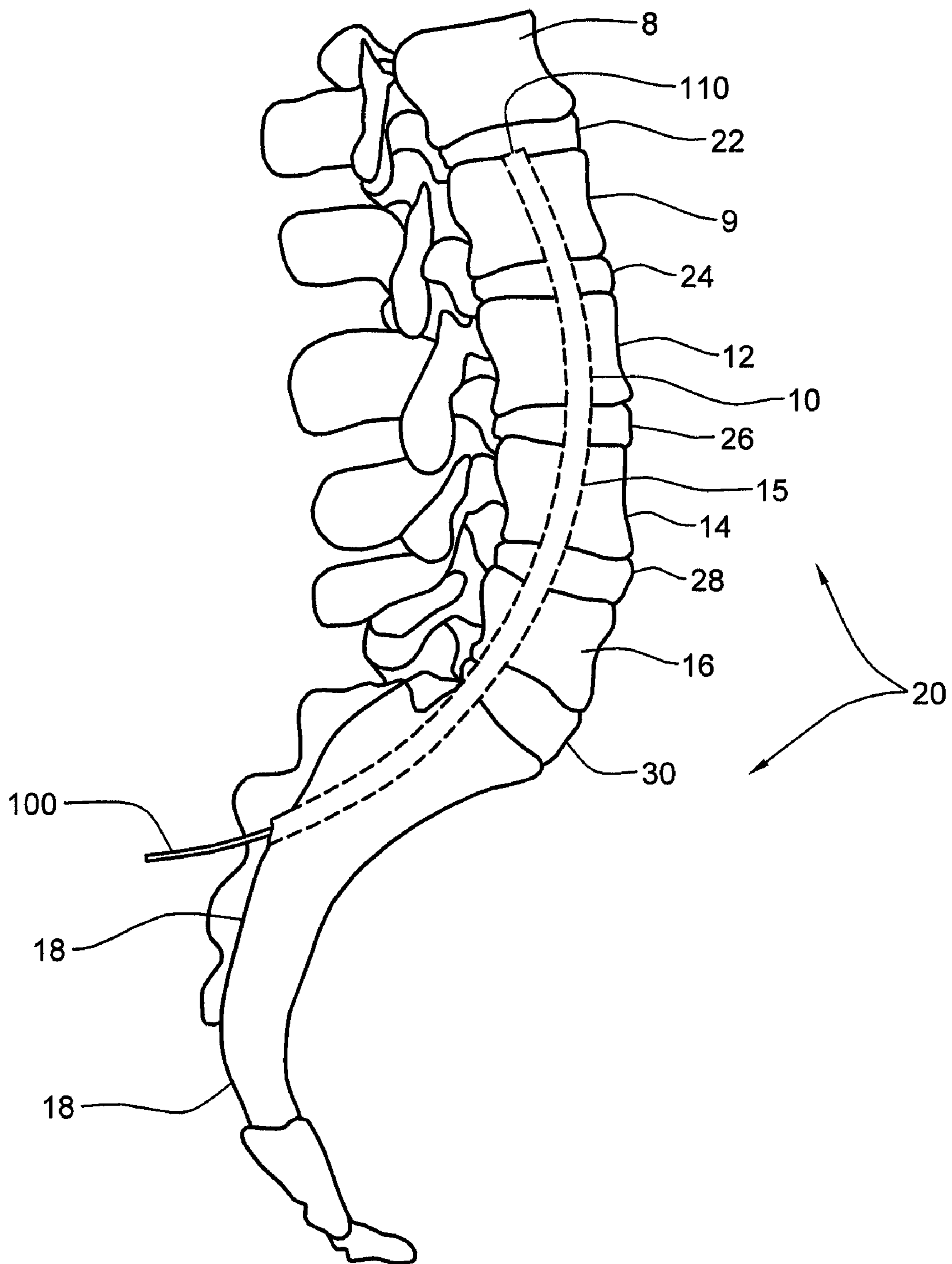


FIG. 2

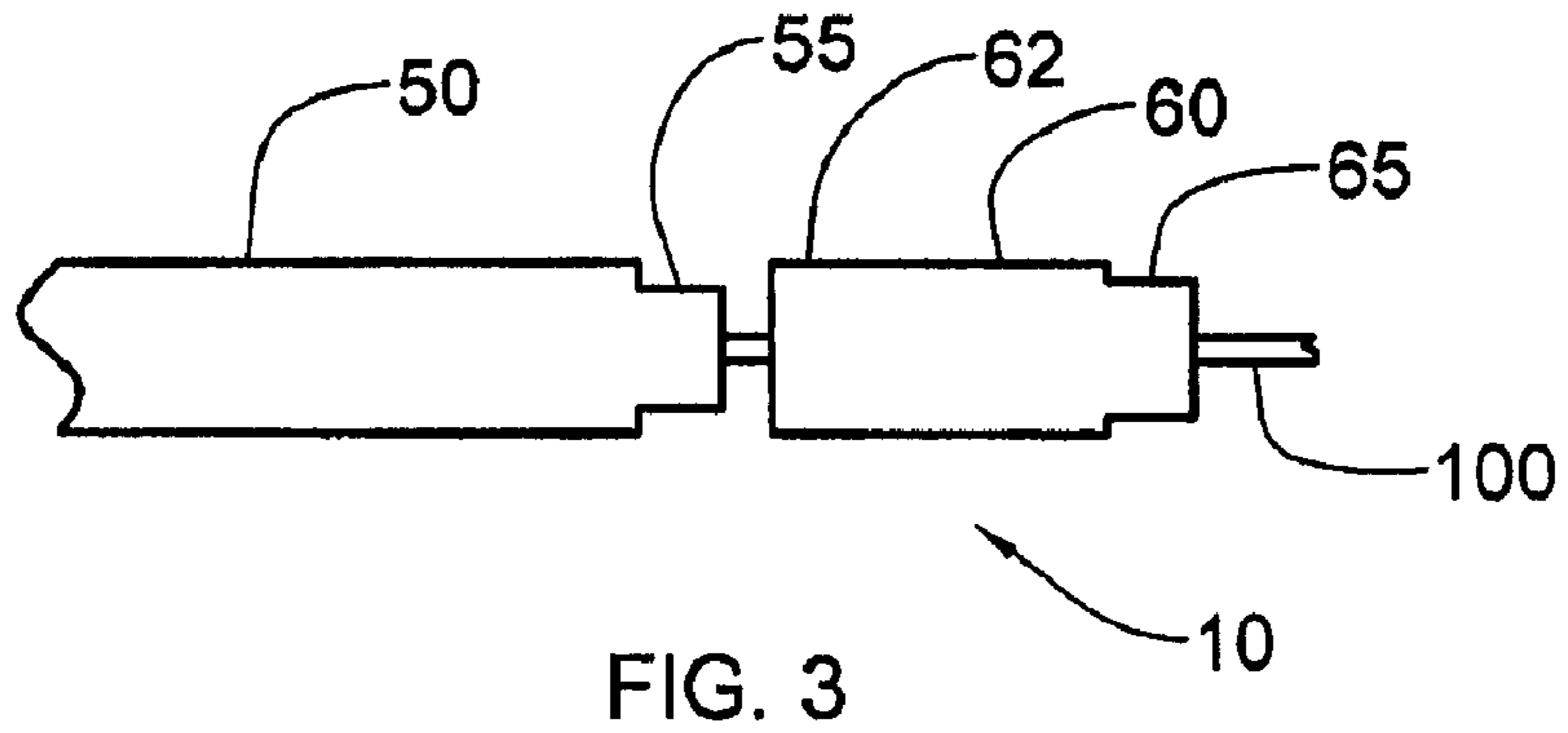


FIG. 3

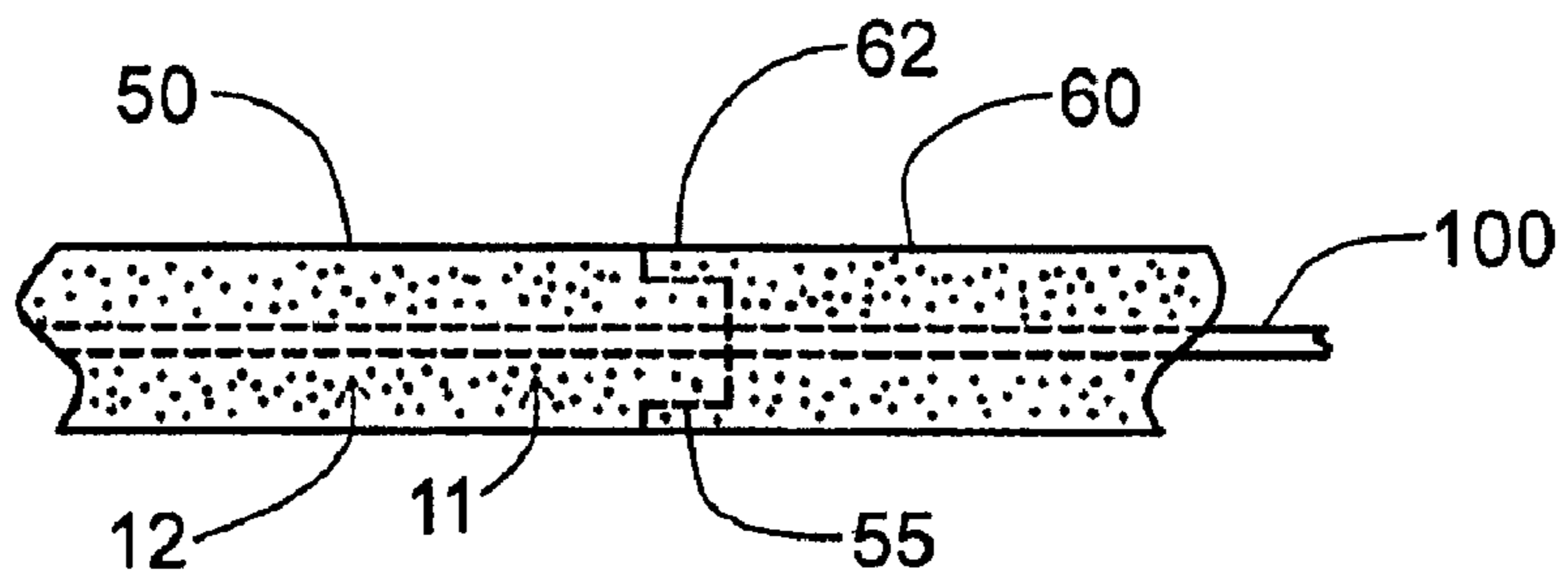


FIG. 4

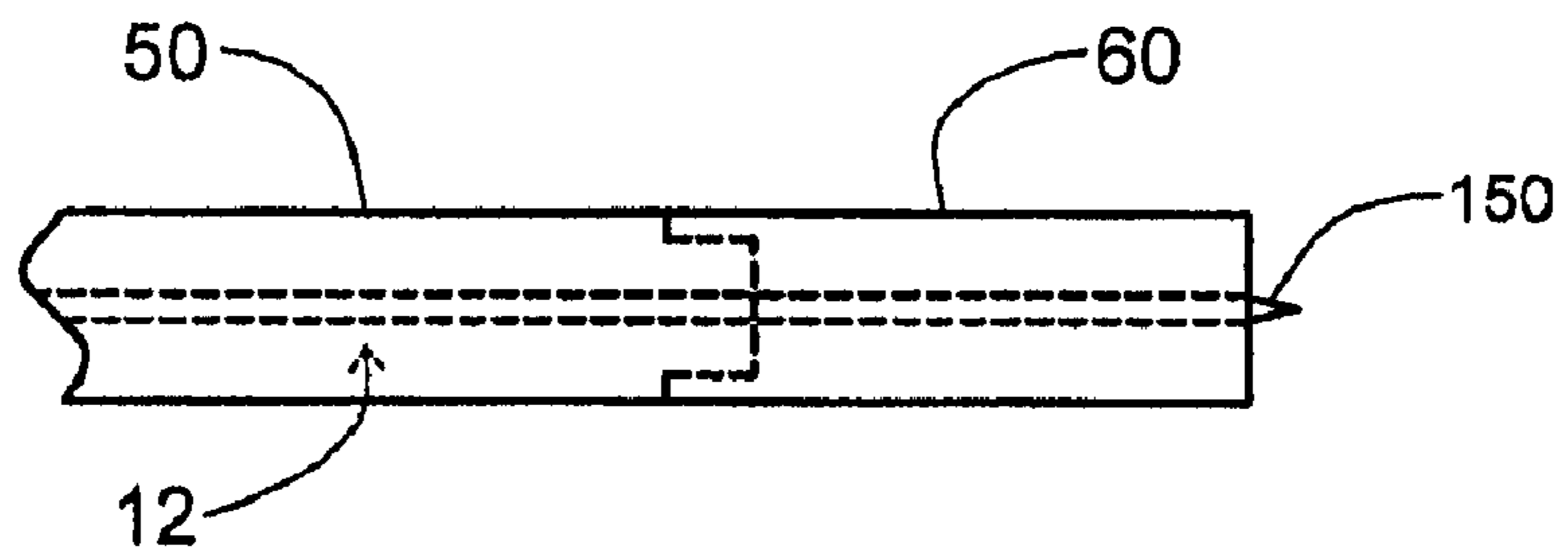


FIG. 5

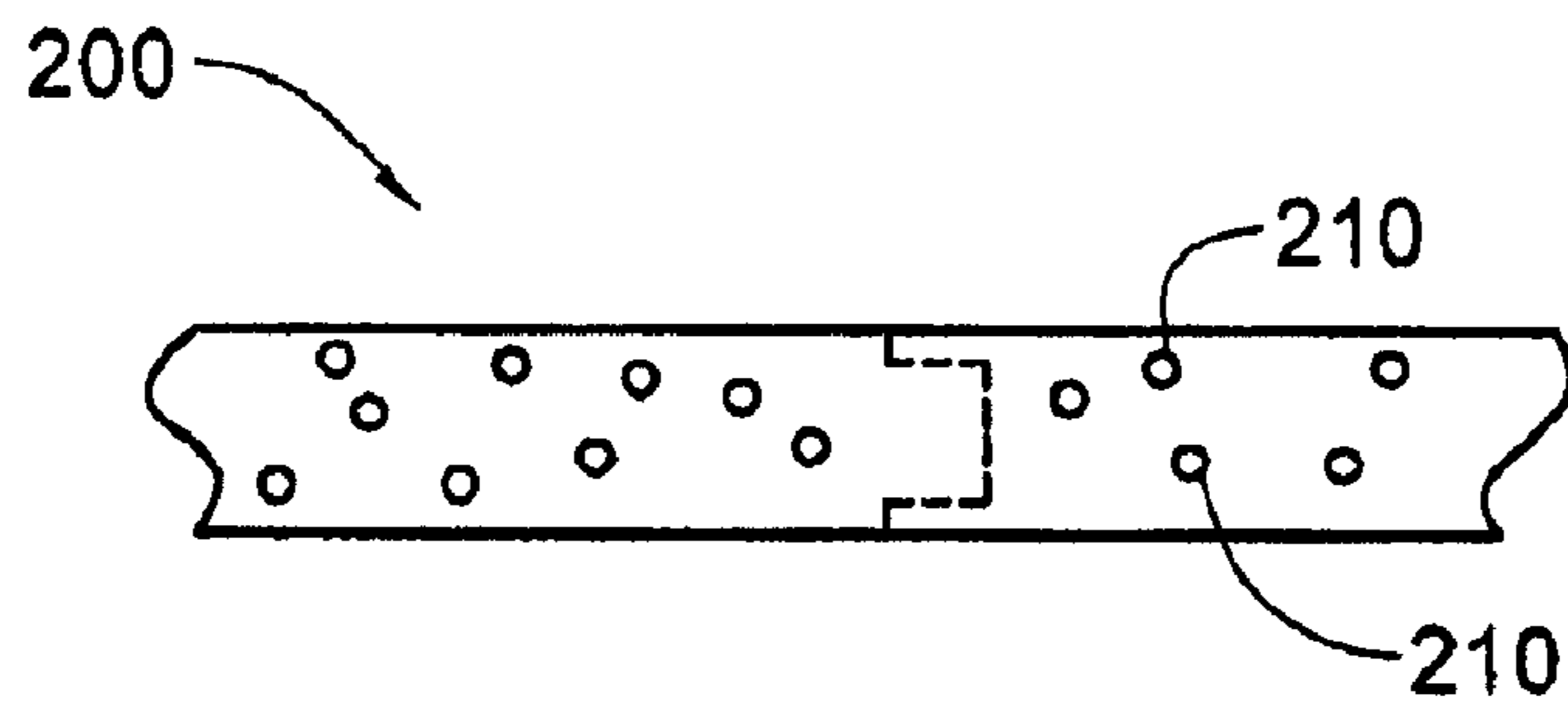


FIG. 6

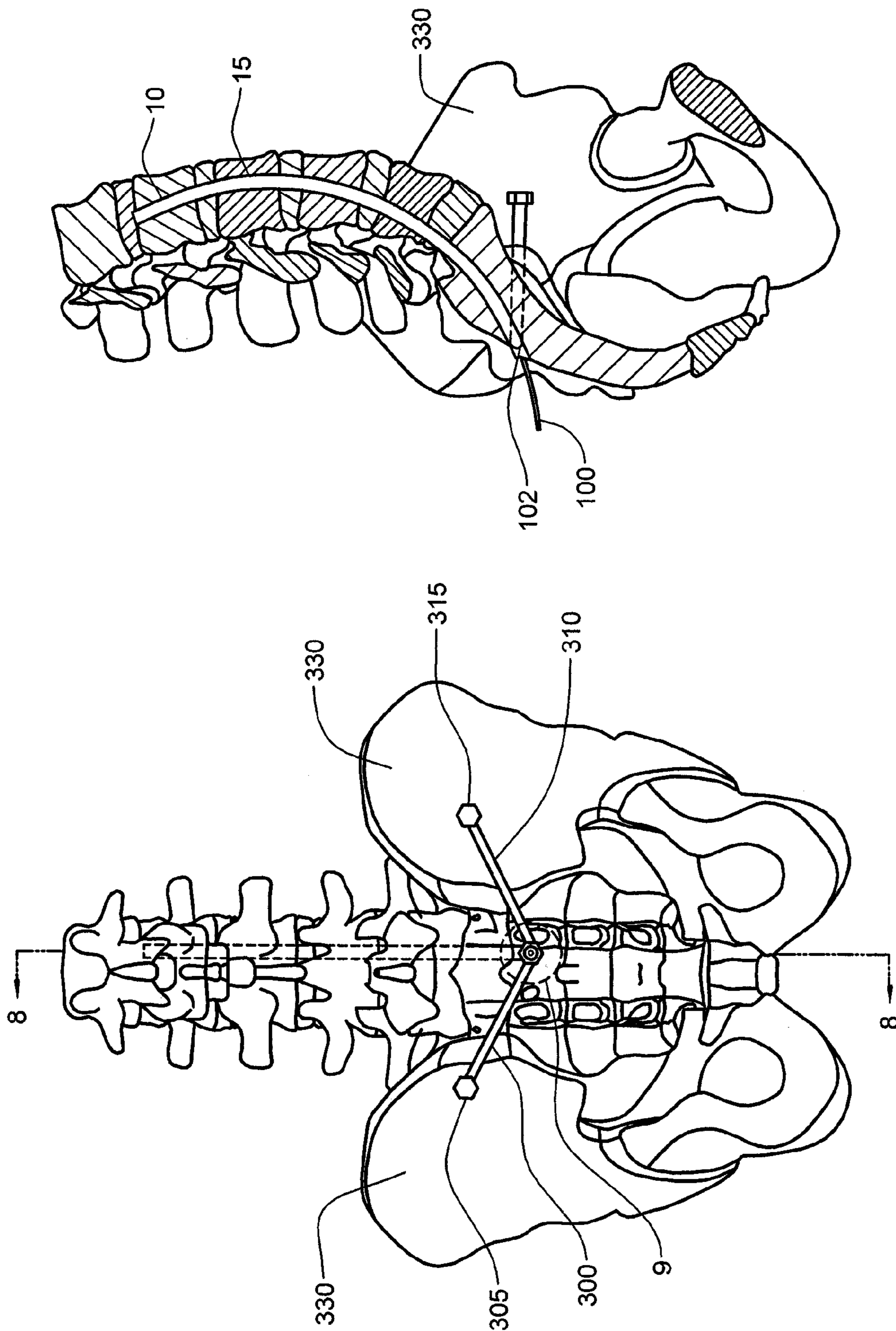


FIG. 8

FIG. 7

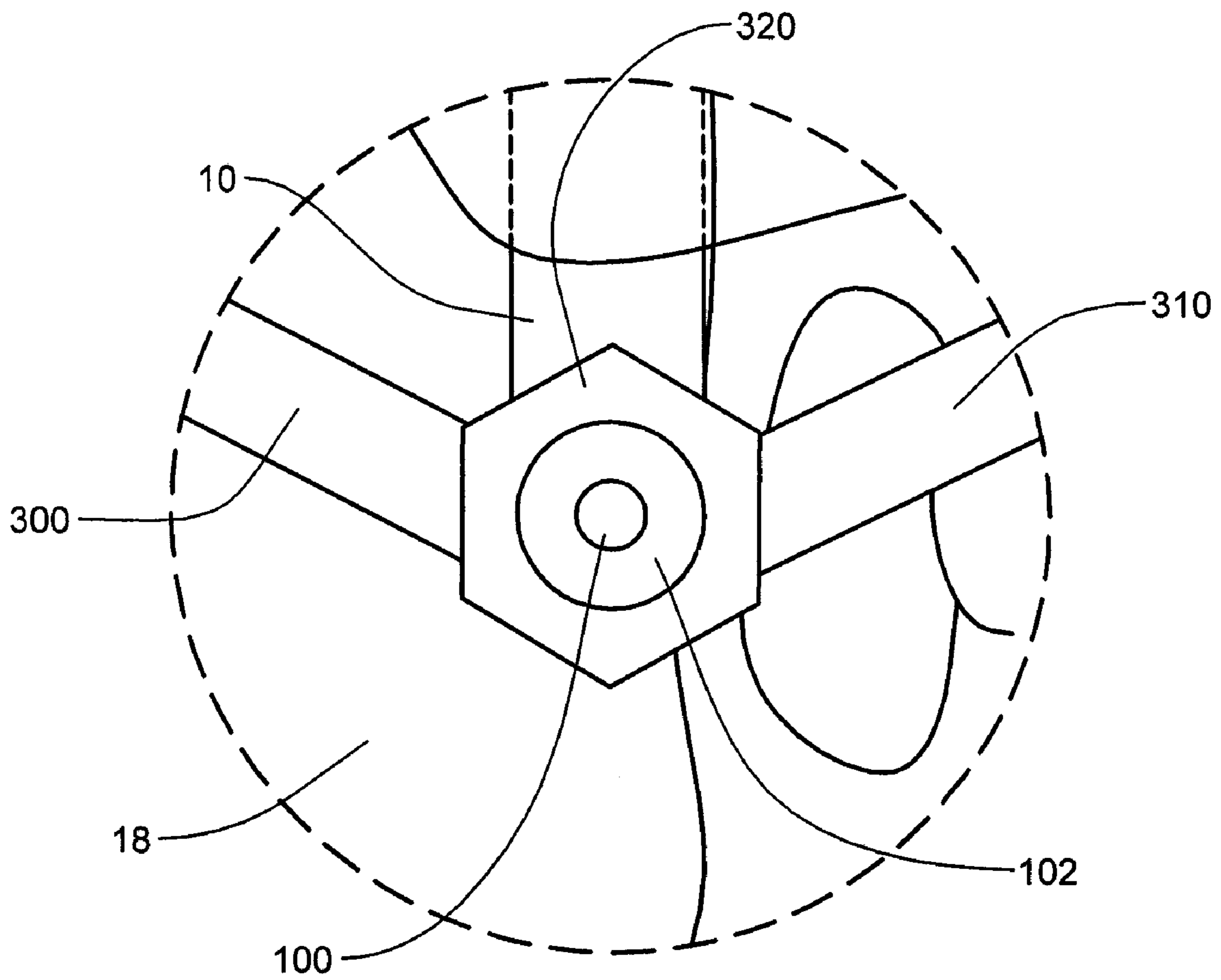


FIG. 9

1**SYSTEMS AND METHODS FOR USE IN
SPINAL SUPPORT**

TECHNICAL FIELD

The present invention relates generally to the field of surgery and medical implants, and more particularly, to surgical tools and methods for supporting a spine.

BACKGROUND OF THE INVENTION

The human spine is a biomechanical structure with thirty-three vertebral members, and is responsible for protecting the spinal cord, nerve roots and internal organs of the thorax and abdomen. The spine also provides structure support for the body while permitting flexibility of motion. A significant portion of the population will experience back pain at some point in their lives resulting from a spinal condition. The pain may range from general discomfort to disabling pain that immobilizes the individual. Back pain may result from a trauma to the spine, be caused by the natural aging process, or may be the result of a degenerative disease or condition.

Back problems sometimes require correcting the curvature of the spine and/or supporting some or all of the spine to minimize pain to the patient. Such conditions include scoliosis, acute fractured collapsing disc, kyphosis and spinal osteo-arthritis, among others.

Thus, a need continues to exist for enhanced systems and methods for supporting and/or correcting a curvature of the spine. The systems and methods disclosed herein address these needs.

SUMMARY OF THE INVENTION

The shortcomings of the prior art are overcome and additional advantages are provided, in one aspect, through a method for use in supporting a spine which includes forming a pathway in the spine by removing a plurality of portions of a plurality of vertebrae of the spine, and the pathway being configured to receive a supporting structure. The supporting structure is inserted into the pathway and through the plurality of vertebrae.

In another aspect the present invention provides a spine-supporting structure system which includes a supporting structure for supporting a spine and a pathway through a plurality of vertebrae of the spine. The supporting structure is inserted into the pathway and through the plurality of vertebrae to support the spine.

In yet another aspect the present invention provides a supporting structure for a spine which includes a plurality of segments configured to form a supporting structure configured to be inserted into a spinal pathway created in a plurality of vertebrae of the spine. A first segment of the plurality of segments has a first end and a second end. A second segment of the plurality of segments has a third end and a fourth end. The first end is engageable with the third end to connect the first segment to the second segment. A cord is received in a first interior of the first segment and a second interior of the second segment. The cord is coupled to the first segment and the second segment and provides stiffness to the first segment and the second segment to support the spine of the person when the plurality of segments is inserted into the spinal pathway.

Further, additional features and advantages are realized through the techniques of the present invention. Other

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embodiments and aspects of the invention are described in detail herein and are considered a part of the claimed invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter, which is regarded as the invention, is particularly pointed out and distinctly claimed in the claims at the conclusion of the specification. The foregoing and other objects, features, and advantages of the invention will be apparent from the following detailed description of preferred embodiments taken in conjunction with the accompanying drawings in which:

FIG. 1 is a side elevational view of a lower portion of the spine of a human;

FIG. 2 is a cross-sectional view of the portion of the spine of FIG. 1 further including a supporting structure inserted into the spine, in accordance with an aspect of the present invention;

FIG. 3 is a side elevational view of a portion of the supporting structure of FIG. 2, in accordance with an aspect of the present invention;

FIG. 4 is another side elevational view of a portion of the supporting structure of FIG. 3 further showing interior details in phantom, in accordance with an aspect of the present invention;

FIG. 5 is a side elevational view of another embodiment of a portion of a supporting structure further including a cutting tool, in accordance with an aspect of the present invention;

FIG. 6 is a side elevational view of another embodiment of a portion of a supporting structure further including a plurality of leaching holes, in accordance with an aspect of the present invention;

FIG. 7 is a rear elevational view of another embodiment of the supporting structure of FIG. 1 further including connecting portions connecting the supporting structure to the ilium;

FIG. 8 is a side cross-sectional view of the supporting structure and connecting portions of FIG. 7; and

FIG. 9 is an enlarged elevational view of a portion of the structure and connecting portions of FIG. 7.

BEST MODE FOR CARRYING OUT THE
INVENTION

In accordance with the principles of the present invention, a spinal supporting system, and methods for use in supporting a spine, are provided.

Referring to FIG. 1, a portion of a spinal column 20 is shown. As depicted, spinal column 20 includes a lumbar region 2, a sacral region 4, and a coccygeal region 6. As is known in the art, spinal column 20 also includes a cervical region and a thoracic region. For clarity and ease of discussion, the cervical region and the thoracic region are not illustrated.

As depicted in FIG. 1, lumbar region 2 includes a first lumbar vertebra 8, a second lumbar vertebra 9, a third lumbar vertebra 12, a fourth lumbar vertebra 14, and a fifth lumbar vertebra 16. Sacral region 4 includes a sacrum 18. Further, coccygeal region 6 includes a coccyx 13. As depicted in FIG. 1, a first intervertebral lumbar disc 22 is disposed between the first lumbar vertebra 8 and the second lumbar vertebra 9. A second intervertebral lumbar disc 24 is disposed between the second lumbar vertebra 9 and the third lumbar vertebra 12. A third intervertebral lumbar disc 26 is disposed between third lumbar vertebra 12 and fourth lumbar vertebra 14. Further, a fourth intervertebral lumbar disc 28 is disposed between fourth lumbar vertebra 14 and the fifth lumbar vertebra 16.

Additionally, a fifth intervertebral lumbar disc **30** is disposed between fifth lumbar vertebra **16** and the sacrum **18**.

As depicted in FIG. 2, a system or structure **10** for supporting spinal column **20**, or a portion thereof, may be inserted into a pathway **15** or channel in spinal column **20**. Pathway **15** may be cylindrical and may extend through one or more portions of spinal column **20**. For example, pathway **15** may extend percutaneously through intervertebral disc(s) and vertebral bod(ies) of spinal column **20**. For example, pathway **15** may extend through sacrum **18**, fifth lumbar vertebra **16**, fourth lumbar vertebra **14**, third lumbar vertebra **12**, and to a top extent of second lumbar vertebra **9** as depicted in FIG. 2.

A spinal supporting structure (e.g., supporting structure **10**) may be made up of a plurality of segments engaged with one another to provide support to the spine and/or promote a desired spinal curvature. For example, structure **10** may include a first segment **50** and second segment **60** as depicted in FIGS. 3-4. The segments may be engageable with one another such that the segments provide structural support to one another and a spinal column (e.g., spinal column **20**, FIGS. 1-2) when they are inserted therein. For example, segment **50** may include a narrowed end **55** receivable within a receiving end **62** of segment **60** wherein receiving end **62** has a diameter slightly larger than narrowed end **55**. Second segment **60** may also have a narrowed end **65** receivable within a receiving end (not shown) of another segment (not shown) of a spinal supporting structure (e.g., supporting structure **10**). Further segments may be connected to one another in a similar manner to form a supporting structure (e.g., supporting structure **10**). Alternatively, such segments could be connected in a different manner. For example, in an unillustrated embodiment one end of each individual segment could include an outer thread while an opposite end could include an internal thread such that the segment could be connected on each end to other such threaded segments.

Supporting structure **10** may also include a cord **100** configured to allow the stiffening or tightening of a plurality of segments (e.g., segment **50** and segment **60**) connected to one another. For example, cord **100** may be connected to one or more ends (e.g. a first end **110**) of supporting structure **10**. The plurality of segments may be loosely or flexibly connected to one another as depicted for example relative to segment **50** and segment **60** in FIG. 3. By applying tension to cord **100** and/or applying opposing pressure to one or more segments (e.g., segment **50** and segment **60**) of a supporting structure (e.g., support structure **10**), the supporting structure may be stiffened and may provide support to one or more vertebrae or portions along spine **20**. For example, such a stiffening or tightening of supporting structure **10** may cause first segment **50** and second segment **60** to engage and abut one another such that narrowed end **55** is received in receiving end **62**. Such stiffening or tightening may also cause supporting structure **10** as a whole to form a desired shape for promoting a correct curvature of the spine. Cord **100** may also hold together the segments making up supporting structure **10** while allowing flexibility to allow freedom of movement of a patient having the supporting structure inserted into his/her spinal column. For example, cord **100** could be flexible and/or resilient to allow the segments making up the support structure to be held together while still allowing movement between the segments thereby allowing freedom of movement for the patient. In another example, the cord could be more rigid to minimize such flexibility and freedom of movement between the segments.

A supporting structure (e.g., supporting structure **10**) could be inserted into the spinal column to provide support and/or a correct curvature thereto as described. More specifically, the

placement of the supporting structure within the pathway (e.g., pathway **15**) allows the supporting structure to directly support the vertebrae of spinal column **20** by direct contact therewith. For example, the frictional contact of the supporting structure with the spinal column may provide support thereto to correct the curvature and/or vertically support portions of spinal column **20**. Further, an end (e.g., end **110**) of the supporting structure (supporting structure **10**) may directly vertically support a portion (e.g., second lumbar vertebra **9** as depicted in FIG. 2) of the spinal column which it contacts. Also, the supporting structure could remain permanently within the spinal column to provide the support and/or promote the correct curvature of the spine. Alternatively, the supporting structure could be removed when the correct curvature of the spine has been achieved or support for the spine is no longer needed. Further, a supporting structure may be removed and another substituted therefor in the event that a different curvature promoting feature or different supporting structure is desired. For example, the curvature of a portion of a spine may be corrected while another requires further correction. In such a situation, a supporting structure may be substituted by another supporting structure of a different shape and/or size.

An end of a supporting structure (e.g., supporting structure **10**) may also include a cutting tool for removing portions of the spine to create a pathway for the supporting structure therein. For example, second segment **60** could include a cutting end **150** as depicted in FIG. 5. A supporting structure (e.g., support structure **10**) may be rotated by a user (e.g., a surgeon) to cause the rotation of cutting end **150** to create the pathway (e.g., pathway **15**) through the bodies of the spinal column. The supporting structure may be removed from the pathway to allow cutting end **150** to be removed therefrom and the supporting structure (e.g., supporting structure **10**) could then be reinserted into the pathway (e.g., pathway **15**) to provide desired support and/or curvature correction. Alternatively, a cutting end (e.g., cutting end **150**) may be connected to the supporting structure such that the cutting end may be removed via a cord through the interior of the supporting structure. As described above, in one unillustrated embodiment the segments may be connected to one another via threaded connections, and such threadedly connected segments may be rotated to allow the movement of such a cutting tool (e.g., cutting end **150**) to create a pathway, such as pathway **15**. Further, in another unillustrated example a cutting end or mechanism (not shown) could be remotely powered via a power cord (not shown) running through the interior of the supporting structure.

Also, after supporting structure **10** has been inserted into pathway **15**, a flowable curable biocompatible material **11** may be injected or inserted into an interior **12** (FIGS. 4-5) of supporting structure **10**. The curable material may provide further structure and/or resiliency to the supporting structure. For example, the curable material could be a rapidly curing, tear resistant elastomer, such as a silicone material. Such a curable material may be used in conjunction with, or instead of, the cord (e.g., cord **100**) described above. Further, the curable material could be formed of any other type of material which provides a desired property such as stiffness, resiliency, or flexibility to a supporting structure. In another example a supporting structure (e.g., structure **10**) may receive a hydrophilic or expandable material for providing structure and/or resiliency to the supporting structure. A hydrophilic material could be encased in a permeable material and such material would swell and become stiffer as it absorbs water from pathway **15** when received therein. In a further example, a slurry of metallic particles could be

received in supporting structure **10** to provide structure and/or resiliency thereto. The slurry of metallic particles may become stiffer by applying an electrical current thereto as described in co-owned U.S. patent application Ser. No. 11/170,554, entitled "Fixation Systems with Modulated Stiffness", and filed on Jun. 30, 2005.

A plurality of segments (e.g., segment **50** and segment **60**) of a supporting structure (e.g., supporting structure **10**) may be configured (e.g., shaped and dimensioned) such that the supporting structure (e.g., supporting structure **10**) as a whole (i.e., when the segments are connected to, or engaged with, one another) has a shape which promotes a correct curvature of a spine of the patient into which structure **10** is inserted. For example, each of such individual segments may have differing individual shapes and sizes to allow the supporting structure as a whole to have a particular desired shape. The shape of the individual segments, and/or supporting structure as a whole, may promote the correct curvature of the spine of a patient having scoliosis or another undesirable curvature of the spine.

Also, the supporting of the spine described above by a supporting structure (e.g., supporting structure **10**) could include distracting portions (e.g., vertebrae) of a spine relative to one another. For example, such distraction may be utilized in the event of a patient having a collapsed disc, e.g., an acute fractured collapsing disc. Also, the supporting structure could provide such distraction while being flexible at other locations with the spinal column for example, an end (e.g., end **110**) of a supporting structure (e.g., supporting structure **10**) may provide such distraction by supporting a disc or vertebra adjacent a damaged disc while the remainder of the supporting structure could remain flexible and/or resilient.

In another example, a supporting structure **200** could include a plurality of radial openings **210** as depicted for example in FIG. 6. The openings may allow the leaching of fusion-promoting proteins (e.g., BMP) from an interior (not shown) of the supporting structure to an exterior thereof in spinal column **20**. The proteins may stimulate fusion of the supporting structure with one or more vertebrae of spinal column **20** thereby promoting the support and/or correct curvature of the vertebrae of the spinal column. Similar to supporting structure **10**, supporting structure **200** may be formed of a plurality of segments (e.g., segment **250** and segment **260**). When such fusion-promoting proteins are utilized such that they may leach from the interior of the supporting structure into the pathway or spinal column, the supporting structure would permanently remain (i.e., not be removed) within spinal column **20** to provide support thereto.

In a further example, a continuous and/or uniform (e.g., not formed of a plurality of segments) supporting structure (not shown) could be inserted into a pathway (e.g., pathway **15**). Such continuous and/or uniform supporting structure could include a cutting tool or could be inserted into such a pathway created in another manner. Also, a flowable curable biocompatible material may be inserted or injected into a cavity (not shown) of the continuous and/or uniform supporting structure to provide the described support and/or resiliency thereto. Further, the continuous and/or uniform supporting structure could be flexible and/or resilient. Moreover, the cavity of such a continuous and/or uniform supporting structure could receive a hydrophilic material, expandable material, or a slurry of metallic particles as described above.

In yet another example depicted in FIGS. 7-9, supporting structure **10** may have an end **102** which is configured (e.g., threaded) to engage a nut **320** or other means of fastening to structure **10**. End **102** and nut **320** may be connected to lateral

connectors **300** and **310** which may also be connected to anchors or screws **305** and **315** connected to opposite portions of an ilium **330**. The connection of connectors **300** and **310** to end **102** inhibits movement (e.g., rotation and/or lateral movement) of supporting structure **10** within spinal column **20** by anchoring structure **10** to ilium **330**. For example, the connection of structure **10** to ilium **330** via connectors **300**, **310** and screws **305**, **315** may inhibit movement of structure **10** within pathway **15** and laterally in a direction perpendicular to pathway **15**. Further, in an unillustrated embodiment, cord **100** could engage with a nut, such as nut **320**, to tighten segments (e.g., segment **50** and segment **60**) of structure **10** relative to each other to promote rigidity and stiffness of structure **10**. In such an example, cord **100** could be threaded (e.g., have external threads to engage nut **320**) and could be made of a material which is flexible enough to allow it to be threaded (e.g., inserted) within structure **10** but also rigid enough to supply resistance to a tightening of nut **320**. Also, structure **10** could be connected to ilium **330**, or another bone in the vicinity of pathway **15** to provide stability to structure **10** in any number of other ways which inhibit movement of structure **10**.

Also, it will be understood to one skilled in the art that a supporting structure (e.g., structure **10**) may be inserted into and/or be located at any of various locations within spinal column **20** and may provide support thereto. For example, instead of being inserted through sacrum **18** as described above, the supporting structure may be inserted into spinal column **20** at another point along the spinal column to provide support and/or correction of the curvature of the spinal column. Also, in addition to the creation of the pathway (e.g., pathway **15**) described above via a cutting tool, such pathway could be formed in any manner known by those skilled in the art which creates a pathway having a desired size and dimension for receiving a supporting structure (e.g., supporting structure **10**) for supporting, and/or correcting the curvature of, the spinal column. Further, the supporting structure could be formed of any number of materials which is biocompatible and capable of providing such support and curvature correction. Moreover, the pathway could be created utilizing a lateral x-ray image of spinal column **20**. Thus, some or all of the supporting structure may be formed of a material visible to such a lateral x-ray. Further, it will be understood by one skilled in the art that a supporting structure (e.g., supporting structure **10**, supporting structure **200**) could be formed in any shape (e.g., a cylindrical shape, a tubular shape, a continuous or non-continuous shape) which allows the supporting structure to support and/or correct a curvature of a spinal column.

Although preferred embodiments have been depicted and described in detail herein, it will be apparent to those skilled in the relevant art that various modifications, additions, substitutions and the like can be made without departing from the spirit of the invention and these are therefore considered to be within the scope of the invention as defined in the following claims.

The invention claimed is:

1. A method for use in supporting a spine, the method comprising:
 - forming a pathway in a spine by removing a plurality of portions of a plurality of vertebrae of the spine with a supporting structure including a cutting tool on a front end of the supporting structure, the supporting structure comprising a plurality of segments oriented in a non-interconnected state;
 - stiffening the supporting structure by orienting the plurality of segments in an interconnected state in the pathway

along the plurality of vertebrae to provide structure to the spine to promote a correct curvature of the spine; and inhibiting movement of the stiffened support structure in the pathway by connecting the supporting structure to an anchor secured to bony structure adjacent the pathway.

2. The method of claim 1, wherein the stiffening the supporting structure comprises engaging ends of the plurality of segments with each other.

3. The method of claim 2, wherein the stiffening the supporting structure further comprises tightening a cord inserted within a cavity of the plurality of segments.

4. The method of claim 1, further comprising the step of injecting a curable material into a cavity of the supporting structure and allowing the material to cure to stiffen the supporting structure.

5. The method of claim 1, wherein the stiffening the supporting structure further comprises distracting a first vertebra of the plurality of vertebrae from a second vertebra of the plurality of vertebrae.

6. The method of claim 1, wherein the removing the plurality of portions comprises removing a portion from a sacrum and a plurality of lumbar vertebrae of the spine.

7. The method of claim 1, wherein the forming the pathway comprises forming the pathway utilizing a lateral X-ray image of the spine to determine a desired direction of the pathway through the spine when removing the plurality of portions of the plurality of vertebrae of the spine.

8. The method of claim 1, wherein the forming the pathway comprises utilizing the cutting tool on the front end of the supporting structure to remove the plurality of portions of the plurality of vertebrae of the spine to form the pathway.

9. The method of claim 1, further comprising providing openings in the supporting structure to promote leaching of fusion stimulating proteins from an interior of the supporting structure.

10. The method of claim 1, wherein the forming the pathway comprises forming the pathway to have a shape promoting a correct curvature of the spine.

11. The method of claim 1, wherein the supporting structure comprises a tubular supporting structure.

12. The system of claim 1, wherein a first end of the segments includes a narrowed end and a second end of the segments include a receiving end, wherein when the segments are interconnected the narrowed end of one respective segment fits within the receiving end of another segment.

13. The method of claim 1, wherein the forming the pathway comprises utilizing the cutting tool on the front end of the supporting structure to remove the plurality of portions of the plurality of vertebrae of the spine to form the pathway, and further comprising removing the cutting tool through the interior of the support structure after forming the pathway.

14. The method of claim 1, wherein:

the stiffening the supporting structure further comprises tightening a cord inserted within a cavity of the plurality of segments; and

inhibiting movement of the stiffened support structure includes threading the anchor to an end of the cord.

15. A spine-supporting structure system comprising:

a supporting structure for supporting a spine comprising a plurality of segments, each of said plurality of segments having a first end sized and configured to be received within a second end of another segment of said plurality of segments and wherein said plurality of segments are connected to each other to form an elongated shape promoting a correct curvature of the spine, wherein when said segments are connected to each other it causes said support structure to stiffen in said shape;

wherein the support structure is sized and configured to fit within a pathway formed through a plurality of vertebrae of the spine; and

wherein said supporting structure includes a cutting tool on a front end of said supporting structure, said cutting tool configured to remove a portion of the plurality of vertebrae of the spine to form the pathway;

wherein said cutting tool is connected to a cord extending through said supporting structure to a rear end of said supporting structure so that said cutting tool is removed through an interior of said support structure after forming the pathway.

16. The system of claim 15, further comprising a first segment of said plurality of segments and a second segment of said plurality of segments, wherein said end of said first segment has a diameter smaller than said second end of said second segment.

17. The system of claim 15, wherein said supporting structure comprises a cavity and said cord is located in said cavity.

18. The system of claim 15, wherein said supporting structure comprises a cavity and a curable material injected into said cavity to stiffen the supporting structure.

19. The system of claim 15, wherein said supporting structure comprises a plurality of openings providing communication between an interior of said supporting structure and said pathway to promote leaching of fusion stimulating proteins from said interior to the pathway.

20. The system of claim 15, wherein said supporting structure comprises a tubular supporting structure.

21. The system of claim 15, wherein the pathway comprises a pathway through a sacrum and a plurality of lumbar vertebrae of the spine.

22. A supporting structure system for a spine, the system comprising:

a plurality of segments configured to form a supporting structure and configured to be inserted into a spinal pathway created in a plurality of vertebrae of the spine; a first segment of said plurality of segments having a first end and a second end;

a second segment of said plurality of segments having a third end and a fourth end;

said first end engageable with said third end to connect said first segment to said second segment;

a cord received in a first interior of said first segment and a second interior of said second segment, said cord coupled to said first segment and said second segment and providing stiffness to said first segment and said second segment to support the spine when said plurality of segments is inserted into the spinal pathway; and

a cutting tool located on an end of at least one of said first segment and said second segment to allow the pathway to be created by a user manipulating the system; and

an anchor threadingly engaged to said cord that is engageable to bony structure of the spine to inhibit movement of said support structure when inserted into the spinal pathway.

23. The system of claim 22, wherein said cord provides stiffness to said first segment and said second segment and allows movement of said first segment relative to said second segment to provide flexibility to said supporting structure.

24. The system of claim 22, further comprising a curable material in said first interior and said second interior to provide at least one of stiffness and flexibility to said first segment and said second segment.

25. The system of claim 22, further comprising radial holes in at least one of said first segment and said second segment to allow fluid communication of fusion-promoting materials from at least one of said first interior and said second interior to the pathway.